K071551

AUG 30 2007

Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter	Biomet *3i*, Inc. 4555 Riverside Palm Beach Gardens, FL 33410
Contact	Diana Taylor Manager, Regulatory Affairs Biomet *3i*, Inc. 4555 Riverside Palm Beach Gardens, FL 33410 Tel. 561-776-6857 Fax. 561-776-6852
Date Prepared	June 5, 2007
Device Name	QuickBridge™ Cylinder and Cap
Classification Name	Endosseous dental implant abutment
Device Classification	Class II Dental Devices Panel 21 CFR § 872.3630
Legally Marketed Predicate Devices	Certain Provide Temporary Cylinder, K061177, 5/16/06
Device Description	The QuickBridge provisional components consist of a non-hexed titanium alloy cylinder and a PEEK Cap. The titanium cylinder threads onto Biomet 3i Conical Abutments that have a 4.8 mm margin diameter. The QuickBridge Cap is made of PEEK and snaps over the QuickBridge Cylinder to allow it to be picked up in a provisional bridge for an immediate load restoration.

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Indications for Use	The QuickBridge System is intended to be mated with BIOMET 3i conical abutments for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or fully edentulous patient. The QuickBridge System is intended for use to support multiple unit prostheses in the mandible or maxilla for up to 180 days during endosseous and gingival healing.
Conclusion	The design modifications for the proposed QuickBridge Cylinder and Cap were completed under Quality System Design Controls in accordance with 21 CFR 820.30. Appropriate verification and validation activities were performed to provide assurance that QuickBridge Cylinder and Cap remain substantially equivalent to the predicate Provide Temporary Cylinder with the Provide Abutment, and the modifications have not changed the intended use, altered the fundamental scientific technology or the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Diana Taylor
Manager, Regulatory Affairs
Biomet 3i, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

AUG 3 0 2007

Re: K071551
Trade/Device Name: QuickBridge Cylinder and Cap
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: June 5, 2007
Received: June 6, 2007

Dear Ms. Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

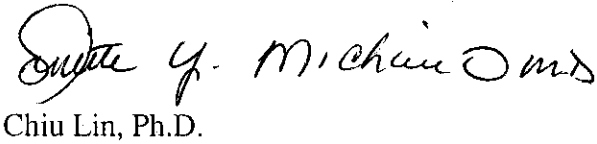
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071551

Device Name: QuickBridge Cylinder and Cap

Indications for Use:

The QuickBridge System is intended to be mated with BIOMET *3i* conical abutments for use as an accessory to endosseous dental implants to support a prosthetic device in a partially or fully edentulous patient. The QuickBridge System is intended for use to support multiple unit prostheses in the mandible or maxilla for up to 180 days during endosseous and gingival healing.

Prescription Use **X** (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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